

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

**3001. Misbranding of amphetamine hydrochloride tablets. U. S. v. Charles R. Wirth (Wirth Drug Store). Plea of nolo contendere. Fine, \$300; defendant placed on probation for 1 year. (F. D. C. No. 28098. Sample Nos. 22021-K, 23668-K, 23987-K, 53665-K.)**

**INFORMATION FILED:** November 15, 1949, Eastern District of Louisiana, against Charles R. Wirth, trading as the Wirth Drug Store, New Orleans, La.

**INTERSTATE SHIPMENT:** Between the approximate dates of November 29, 1948, and January 19, 1949, from Chicago, Ill.

**ALLEGED VIOLATION:** On or about March 8 and April 4 and 6, 1949, and while a number of *amphetamine hydrochloride tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repackaged and sold to various persons, which acts of the defendant resulted in the repackaged *amphetamine hydrochloride tablets* being misbranded. Each container of the repackaged tablets was unlabeled.

**NATURE OF CHARGE:** Misbranding, Sections 502 (b) (1) and (2), the containers of the repackaged *amphetamine hydrochloride tablets* bore no label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), the containers bore no label containing the common or usual name of the tablets, namely, "Amphetamine Hydrochloride"; and, Section 502 (f) (2), the containers bore no labeling containing warnings against use of the tablets in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

**DISPOSITION:** February 1, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$100 on each of the first three counts of the information, suspended the imposition of sentence on count four, and placed the defendant on probation for 1 year.

**3002. Misbranding of Benadryl capsules, sulfathiazole lozenges, and phenobarbital tablets. U. S. v. Argus Chaffin (West End Drug Store), and Cleo Wear. Pleas of nolo contendere. Defendants placed on probation for 1 year. (F. D. C. No. 26712. Sample Nos. 27036-K, 27045-K, 27049-K.)**

**INFORMATION FILED:** June 21, 1949, Western District of Arkansas, against Argus Chaffin, trading as the West End Drug Store, Fort Smith, Ark., and Cleo Wear, a pharmacist.

**INTERSTATE SHIPMENT:** On or about October 3, 1947, and May 7 and October 4, 1948, from the States of Missouri and Indiana into the State of Arkansas.

**LABEL, WHEN SHIPPED:** "Kapseals Benadryl Hydrochloride [or "Lozenges Sulfathiazole" or "Phenobarbital Tablets"] \* \* \* Caution: To be dispensed only by or on the prescription of a physician."

**ALLEGED VIOLATION:** On or about August 31, September 27, and October 4, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused certain quantities of the drugs to be removed from the bottles in which they had been shipped and to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The repackaged *Benadryl capsules* were unlabeled. The other repackaged drugs were labeled "Sulfathiazole Lozenges" and "Phenobarbital ½ Gr."

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (1), the repackaged drugs bore no label containing a statement of the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), they bore no labeling containing directions for use.

Further misbranding, Section 502 (e) (1), the container of the repackaged *Benadryl capsules* bore no label containing the common or usual name of the drug; and, Section 502 (f) (2), the container of the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

**DISPOSITION:** September 30, 1949. Pleas of nolo contendere having been entered, the court placed the defendants on probation for 1 year.

**3003. Adulteration and misbranding of Geo-Mineral. U. S. v. 672 Bottles \* \* \*.**  
(F. D. C. No. 27227. Sample No. 51436-K.)

**LIBEL FILED:** May 18, 1949, Southern District of Indiana.

**ALLEGED SHIPMENT:** On or about February 15, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

**PRODUCT:** 672 3-ounce bottles of *Geo-Mineral* at Anderson, Ind. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

**LABEL, IN PART:** "Geo-Mineral \* \* \* Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

**NATURE OF CHARGE:** Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

**DISPOSITION:** August 8, 1949. Default decree of forfeiture and destruction.

**3004. Misbranding of Gall-Klenz. U. S. v. 27 Gallons \* \* \*.** (F. D. C. No. 27779. Sample Nos. 16285-K, 42343-K.)

**LIBEL FILED:** August 29, 1949, Eastern District of Michigan.

**ALLEGED SHIPMENT:** On or about April 20, May 16, and June 18, 1949, from Des Moines, Iowa.

**PRODUCT:** 27 gallons of a drug, some of which had been repackaged into 288 2-ounce and 6-ounce bottles labeled "Gall-Klenz," at Detroit, Mich., in possession of the F. A. R. Chemical Co.

Examination of the product showed that it contained alcohol, sodium salicylate, phenolphthalein, bile extract, sodium oleate, menthol, and aromatics.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, namely, a circular entitled "Dear Friend" and leaflets entitled "Valuable Knowledge Everyone Should Know," "Bowel-